Title: LIQUID DRUG TRANSFER DEVICE WITH VENTED VIAL ADAPTER

Abstract: Liquid drug transfer devices including a vented vial adapter having a top wall, a downward depending skirt, and a dual lumen puncturing spike. The top wall includes vent apertures in flow communication with an underlying air filter and protective hoods for covering the vent apertures from splashes. The hood-like hoods are preferably quarter sphere shaped with hood apertures facing radial outwards.
— before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))
LIQUID DRUG TRANSFER DEVICE WITH VENTED VIAL ADAPTER

Field of the Invention

The invention relates to liquid drug transfer devices in general and liquid drug transfer devices including a vented vial adapter in particular.

Background of the Invention

US Patent No. 6,139,534 to Niedospial, Jr. et al. illustrates and describes a liquid drug transfer device constituted by a vented vial adapter having a longitudinal vial axis and including a top wall with a series of axial directed vent apertures, an annular air filter underlying the series of vent apertures, a downward depending skirt for telescopically receiving a vial therein, a downward depending central dual lumen puncturing spike and an oppositely directed central liquid transfer port. The dual lumen puncturing spike includes a pair of axial directed adjacent lumens, namely, a liquid transfer lumen and a vent lumen. The liquid transfer port is in flow communication with the liquid transfer lumen. The vent apertures are in flow communication with the vent lumen via the air filter. The vented vial adapter includes an elastomeric pre-split septum for maintaining sterility of vial contents. Use of the vented vial adapter may lead to liquid drug contents inadvertently draining into one or more of the vent apertures or one or more vent apertures being splashed by liquid drug contents, thereby wetting the underlying air filter to the detriment of its operation.

Summary of the Invention

The present invention is directed toward liquid drug transfer devices including a hitherto described vented vial adapter. The present invention is directed towards provisioning such a vented vial adapter with individual protective hoods for covering its vent apertures for precluding liquid drug contents entering a vent aperture due to draining, splashing, and the like, and wetting its underlying air filter to the detriment of its operation. The present invention can include a manually placed cap for placing on a liquid access port for maintaining contents sterility. Alternatively, the present invention can include an elastomeric pre-split septum for maintaining sterility of vial contents.

The present invention can be equally applied to a wide range of liquid drug transfer devices including vented vial adapters for use with different sized vials, namely, 13mm, 20mm, and the like. The liquid drug transfer devices can be constituted by vial adapters per se including female vial adapters, male vial adapters, and the like. Other liquid drug transfer devices include, for example, liquid drug transfer devices illustrated and described in commonly owned US Patent No. 6,558,365 to Zinger et al., in-line liquid drug transfer devices illustrated and described in commonly owned PCT International Publication No. WO 2005/105014, and the like.

Brief Description of Drawings

In order to understand the invention and to see how it can be carried out in practice, preferred embodiments will now be described, by way of non-limiting examples only, with reference to the accompanying drawings in which similar parts are likewise numbered, and in which:

Fig. 1 is a pictorial representation of a syringe, a vial and a vented female vial adapter having a longitudinal vial axis;

Fig. 2 is a top plan view of the vented vial adapter along the longitudinal vial axis;
Fig. 3 is a longitudinal cross section of Figure 1's vented vial adapter along line A-A in Figure 2; Fig. 4 is a longitudinal cross section of Figure 1's vented vial adapter along line B-B in Figure 2; and Fig. 5 is a pictorial representation of a liquid drug transfer device with a detachable vented vial adapter.

**Detailed Description of Preferred Embodiments of the Invention**

Figure 1 shows a syringe 10 constituting a source of physiological fluid, a medicinal vial 20 and a liquid drug transfer device 30 constituted by a vented female vial adapter for use with the syringe 10 and the vial 20. The syringe 10 includes a barrel 11 with a plunger 12 and a male Luer lock connector 13. The syringe 10 can be formed with other types of male connectors. The vial 20 includes an open topped bottle 21 sealed by a vial stopper 22 capped by a metal band 23. The vial 20 contains either a powdered or liquid drug 24 under negative pressure. The syringe 10 typically contains diluent for reconstituting the vial contents 24.

Figures 1 to 4 show the vented female vial adapter 30 has a longitudinal vial axis 31 and includes a transverse top wall 32 having a downward depending skirt 33 with flex members 34 for snap fitting onto the vial 20. The vial adapter 30 includes a downward depending dual lumen puncturing spike 36 for puncturing the vial stopper 22 on snap fitting the skirt 33 on the vial 20. The puncturing spike 36 includes a base 36A towards the top wall 32 and terminates in a spike tip 36B. The puncturing spike 36 includes a pair of axial directed lumens, namely, a liquid transfer lumen 37 and a vent lumen 38. The liquid transfer lumen 37 includes a port 37A towards the spike tip 36B. The vent lumen 38 has a port 38A towards the spike tip 36B.

The vial adapter 30 also includes a central axial directed liquid transfer port 39 oppositely directed to the puncturing spike 36 and in flow communication with the liquid transfer lumen 37. The liquid transfer port 39 terminates in a female Luer connector 41 for screw thread engagement with the
syringe's male Luer lock connector 13. The vial adapter 30 includes a manually placed cap 42 for sealing the female Luer connector 41.

The top wall 32 includes a pair of diametrical opposite axial directed vent apertures 43. An annular air filter 44 is disposed beneath the top wall 32. The vent apertures 43 are in flow communication with the vent lumen 38 via the air filter 44. The air filter 44 filters air entering drawn into the vial 20 on puncturing the vial stopper 22.

The top wall 32 is formed with a pair of protective hoods 46 mounted over the vent apertures 43 for covering the vent apertures 43 in Figure 2's top plan view. The protective hoods 46 are preferably quarter sphere shaped. The protective hoods 46 each have a hood aperture 47 above the top wall 32 and facing radial outwards relative to the longitudinal vial axis 31. The protective hoods 46 preclude liquid drug contents inadvertently wetting the air filter 44 via the vent apertures 43 during use of the vial adapter 30.

Figure 5 shows a US Patent No. 6,558,365 liquid drug transfer device 50 with a detachable vented vial adapter 51 similar to the vented vial adapter 30.

While the invention has been described with respect to a limited number of embodiments, it will be appreciated that many variations, modifications, and other applications of the invention can be made within the scope of the appended claims.
CLAIMS:

1. A liquid drug transfer device for use with a medicinal vial including a bottle containing a medicament, a vial opening stopped by a vial stopper, and a narrow neck intermediate the bottle and the vial opening,

   the liquid drug transfer device comprising a vented vial adapter having a longitudinal vial axis and including a top wall transverse to said longitudinal axis, a substantially cylindrical skirt having flex members resiliently attached to said top wall and downwardly depending therefrom for telescopically slidingly receiving the vial opening therein, an annular air filter disposed beneath said top wall,

   a downwardly depending dual lumen puncturing spike for puncturing the vial stopper for establishing flow communication with the bottle interior, said puncturing spike having a base adjacent said top wall and a puncturing tip, said puncturing tip including a pair of axial directed lumens extending from said base to said puncturing tip, said pair of axial directed lumens including a liquid transfer lumen and a vent lumen,

   a liquid transfer port in flow communication with said liquid transfer lumen,

   at least one axial directed vent aperture formed in said top wall and in flow communication with said vent lumen via said air filter, said liquid transfer port and said at least one vent aperture being in flow communication with the bottle on slidingly receiving the vial in the vial adapter characterized in that

   said top wall is formed with a corresponding number of at least one protective hood as said at least one vent aperture such that each vent aperture of said at least one vent aperture is individually covered by a protective hood of said corresponding number of at least one protective hood in a top plan view of said vented vial adapter along said longitudinal vial axis and

   each said protective hood has a hood aperture facing radial outward with respect to said longitudinal vial axis.
2. The device according to claim 1 wherein each said protective hood has a quarter sphere shape.

3. The device according to either claim 1 or 2 and further comprising a manually placed cap for sealing said liquid access port.
**INTERNATIONAL SEARCH REPORT**

**A. CLASSIFICATION OF SUBJECT MATTER**

INV. A61J1/20

ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

A61J

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal , WPI Data

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

<table>
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<tr>
<th>Category*</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
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<td>US 5 041 105 A (D AL0 HERBERT F [US] ET AL) 20 August 1991 (1991-08-20) the whole document</td>
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**Further documents are listed in the continuation of Box C.**

**See patent family annex.**

* Special categories of cited documents :

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**Date of the actual completion of the international search**

5 July 2011

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